K083214

MAY 12 2009

510(K) Summary (per 21 CFR 807.92)

1. Applicant Information

Date Prepared:	October 30, 2008
Submitter:	AGA Medical Corporation 5050 Nathan Lane North Plymouth, MN 55442 USA
Establishment Registration Number:	2135147
Contact person:	Diane Carroll Regulatory Affairs Associate
Telephone Number:	763.531.3161
Fax Number:	763.647.5932

2. General Device Information

Trade Name:	AMPLATZER® TorqVue® 45°x45° Delivery Sheath
Common Name:	Catheter, Delivery Sheath
Classification Name:	Catheter, Percutaneous
Classification:	Class II, 21 CFR 870.1250
Product Code:	DQY
Predicate Device:	AMPLATZER® TorqVue® Delivery System, K072313, cleared November 2, 2007 Reg. No. 870.1250

3. Device Description

The AMPLATZER® TorqVue® 45°x45° Delivery Sheath is a sterile, single-use, general-purpose sheath that is an extension of the TorqVue Delivery System product line. It is designed to provide a pathway through which a device may be delivered to the chambers of the heart.

The AMPLATZER® TorqVue® 45°x45° Delivery Sheath has a usable length of 100 cm and is available in 9 Fr, 10 Fr, 12 Fr, and 13 Fr sizes (inner diameter). A dilator, which eases penetration of tissue, is packaged with each sheath. The distal end of both the sheath and dilator are curved approximately 45° in two dimensions, resulting in a three-dimensional geometry. The 10 Fr, 12 Fr, and 13 Fr sizes also include a flush adapter that facilitates connection of accessories to the proximal end of the sheath.

The body of each sheath is radiopaque for visibility under fluoroscopy. The sheath is constructed of two segments of different Pebax materials to provide support for device advancement and tip flexibility for vessel engagement. The distal end of the sheath has a soft tip composed of 55-durometer Pebax® to minimize vessel trauma.

4. Intended Use

The AMPLATZER® TorqVue® 45°x45° Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.

5. Comparison to Predicate

The AMPLATZER® TorqVue® 45°x45° Delivery Sheath has the following similarities when compared to the predicate device:

- Indications for Use are similar; the AMPLATZER® TorqVue® 45°x45° Delivery Sheath indications are a subset of the predicate's indications
- Operating principal is the same
- Manufacturing materials and processes are the same
- Sterilization method is the same
- Sterile package materials are the same

6. **Test Data**

The functional characteristics of the AMPLATZER TorqVue® 45°x45° Delivery Sheath are substantially equivalent to the predicate device cited. Bench testing of the AMPLATZER TorqVue® 45°x45° Delivery Sheath included verification of the distal curve dimensions after sterilization, distribution simulation, and six-month accelerated aging.

7. **Summary**

Based on the technical information, intended use, and laboratory verification test information provided, the AMPLATZER TorqVue® 45°x45° Delivery Sheath is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2009

AGA Medical Corporation
c/o Ms. Diane Carroll
Regulatory Affairs Associates
5050 Nathan Lane North
Plymouth, MN 55442-3209

Re: K083214
Trade/Device Name: AMPLATZER® TorqVue® 45° x 45°Delivery Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 4, 2009
Received: May 5, 2009

Dear Ms. Carroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

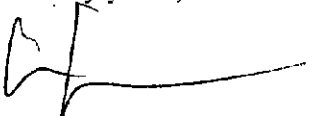
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K083214

Device Name: AMPLATZER TorqVue 45°x45° Delivery Sheath

Indications for Use: The AMPLATZER TorqVue 45°x45° Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.

Prescription Use ___X___ **AND/ OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083214